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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/076,404

Applicant(s)

Ecker et al.

Examiner

Ardin Marschel

Group Art Unit

1631



X Responsive to communication(s) filed on Jul 7, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

X Claim(s) 1-5 and 17-30 is/are pending in the application

~~Of the above, Claim(s) 6-16 have been canceled. ~~are withdrawn from consideration~~~~

Claim(s) _____ is/are allowed.

X Claim(s) 1-5 and 17-30 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, ~~2 sheets~~ (2 sheets)

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Applicants' arguments, filed 7/7/00, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The disclosure is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code. Applicants are required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01. Embedded hyperlinks are present in the specification at pages 32 and 33, for example.

Claims 1-5 and 17-30 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the application of the program DOCK for modeling the interactions of molecules with a macromolecule's binding site, does not reasonably provide enablement for generally discovering the binding site(s) in macromolecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the

Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

This rejection is reiterated from the previous office action, mailed 3/30/00, and as necessitated by amendment due to the newly submitted claims. Applicants firstly argue that the secondary structures of IRE, for example, are easily identified. In response this is moot in overcoming the rejection because it is based on a lack of scope of enablement regarding 3-D structure, and not whether secondary, and non-3-D structure, is readily obtainable. Applicants then argue that a number of commercially available computer programs can be used for the required modeling and point to page 94, line 25, through page 95, line 15. Various sources are cited but without any specific

software noted. Presumably, these sources publish some type of software description as to their products. A lack of specific listing of such particular software leaves unsupported the allegation as to what their capabilities are, especially since it is impossible to choose what is meant to support the allegation of broad enablement of binding site computer modeling beyond DOCK. In order to fully enable the broad scope of the invention, these software items are deemed essential material for such scope broadening and cannot be simply incorporated by reference. See the following paragraph regarding such improper incorporation by reference.

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157; *In re Hawkins*, 486 F.2d 579, 179 USPQ 163; *In re Hawkins*, 486 F.2d 577, 179 USPQ 167.

It is noted that the remainder of the arguments regarding this scope of enablement rejection fails to describe any 3-D modeling beyond utilizing DOCK and thus is non-persuasive in overcoming this rejection. It is lastly noted that a binding site is a 3-D structure into which a compound may fit and be held with some affinity and arguments regarding other structures of macromolecules, RNA or not, such as primary and secondary

structures fail to rise to the binding site 3-D requirements.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 17, 18, 21-23, and 26-28 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Chen et al. (Biochemistry 36:11402[1997]).

Chen et al. is clearly directed to 3-D modeling as summarized in the abstract where a series of lead compounds are evaluated for binding to RNA. These are compared as to binding interactions as well as placed in a hierarchy ranked on their binding ability as described on page 11404, second column, through page 11406, first column, in the RESULTS section. Binding tests are also disclosed. These disclosures anticipate the above listed instant claims. Applicants argue that NMR was utilized for binding measurements in the reference. This is acknowledged but does not negate the fact that computer 3-D modeling was utilized for the 400 compound evaluation which still anticipates the above claims. Applicants then argue that other sites can be evaluated by the instant invention beyond RNA double-helix. This is acknowledged but again does not negate the

fact that the instant claims include modeling as performed in Chen et al. and thus are anticipated. Applicants claims are not limited to exclude the Chen et al. methods. Applicants then argue that the mass spectroscopy type of analysis of compounds is not supported by the reference. This is acknowledged and instant claims that require fragmentation and/or ionization of the mass spectroscopy type are no longer rejected over this reference alone.

The disclosure is objected to because of the following informalities:

In the specification on page 31, line 24, the words "determied" and "inependently" appear to be misspelled.

Correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

October 10, 2000

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER